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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,922	04/12/2001	Frederick Geissmann	1383-0260001	8471

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,922	GEISSMANN ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☒ Other: *Fax cover sheet* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Claims 1-37 are pending.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4-5, 10 and 16, drawn to a method of modulating the immune system of an animal wherein the modulation is **activation** of an antigen-presenting cell using a specific retenoid and a specific cytokine wherein the retenoid is a **pan-RXR agonist SR11237** and pharmaceutically acceptable salts, esters and prodrugs thereof, classified in Class 424, subclass 85.1, subclass 198.1.

II Claims 1-2, 4-5, 10 and 16, drawn to a method of modulating the immune system of an animal wherein the modulation is **activation** of an antigen-presenting cell using a specific retenoid and a specific cytokine wherein the retenoid is a **pan-RXR agonist compound V** and pharmaceutically acceptable salts, esters and prodrugs thereof, classified in Class 424, subclass 85.1, subclass 198.1.

III. Claims 1-2, 4, 6, 10 and 16, drawn to a method of modulating the immune system of an animal wherein the modulation is **activation** of an antigen-presenting cell using a specific

retenoid and a specific cytokine wherein the retenoid is a **RAR antagonist compound II** and pharmaceutically acceptable salts, esters and prodrugs thereof, classified in Class 424, subclass 85.1, subclass 198.1.

IV. Claims 1-2, 4, 6, 10 and 16, drawn to a method of modulating the immune system of an animal wherein the modulation is **activation** of an antigen-presenting cell using a specific retenoid and a specific cytokine wherein the retenoid is a **RAR antagonist compound V** and pharmaceutically acceptable salts, esters and prodrugs thereof, classified in Class 424, subclass 85.1, subclass 198.1.

V. Claims 1-2, 4, 6, 10 and 16, drawn to a method of modulating the immune system of an animal wherein the modulation is **activation** of an antigen-presenting cell using a specific retenoid and a specific cytokine wherein the retenoid is a **RAR antagonist compound VIII** and pharmaceutically acceptable salts, esters and prodrugs thereof, classified in Class 424, subclass 85.1, subclass 198.1.

VI. Claims 1, 3, 7-10 and 16, drawn to a method of modulating the immune system of an animal wherein the modulation is **activation** of an antigen-presenting cell using a specific retenoid and a specific cytokine wherein the retenoid is an **RAR agonist wherein the RAR agonist is an RARα agonist compound I** and pharmaceutically acceptable salts, esters and prodrugs thereof, Class 424, subclass 85.1, subclass 198.1.

VII. Claims 11-13 and 16, drawn to a method of **inducing apoptosis** in a mammalian antigen presenting cell, using synthetic **retinoid RARα agonist compound I** and pharmaceutically acceptable salts thereof, classified in Class 424, subclass 198.1.

VIII Claims 11-12, 14 and 16, drawn to a method of **inducing apoptosis** in a mammalian antigen presenting cell, using synthetic **retinoid RARβ agonist compound III** and pharmaceutically acceptable salts thereof, classified in Class 424, subclass 198.1.

IX. Claims 11-12, 14 and 16, drawn to a method of **inducing apoptosis** in a mammalian antigen presenting cell, using synthetic **retinoid RARβ agonist compound VII** and pharmaceutically acceptable salts thereof, classified in Class 424, subclass 198.1

X. Claims 11-12, 15 and 16, drawn to a method of **inducing apoptosis** in a mammalian antigen presenting cell, using synthetic **retinoid pan-RXR agonist compound SR11237** and pharmaceutically acceptable salts thereof, classified in Class 424, subclass 198.1.

XI. Claims 11-12, 15 and 16, drawn to a method of **inducing apoptosis** in a mammalian antigen presenting cell, using synthetic **retinoid pan-RXR agonist compound V** and pharmaceutically acceptable salts thereof, classified in Class 424, subclass 198.1.

XII. Claims 17-18, 20-21, 26-29 and 34, drawn to a **composition** for modulating the immune system of an animal wherein the modulation is **activating** antigen presenting cell using retinoid **pan-RXR SR11237**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 514, subclass 167.

XIII. Claims 17-18, 20-21, 26-29 and 34, drawn to a **composition** for use in modulating the immune system of an animal wherein the modulation is **activating** antigen presenting cell using retinoid **pan-RXR compound V** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients classified in Class 424, subclass 198.1, subclass 184.1.

XIV. Claims 17-18, 20, 22, 26-29 and 34, drawn to a **composition** for use in modulating the immune system of an animal wherein the modulation is **activating** antigen presenting cell using an **RAR antagonist compound II** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XV. Claims 17-18, 20, 22, 26-29 and 34, drawn to a **composition** for use in modulating the immune system of an animal wherein the modulation is **activating** antigen presenting cell using an **RAR antagonist compound V,** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XVI. Claims 17-18, 20, 22, 26-29 and 34, drawn to a **composition** for use in modulating the immune system of an animal wherein the modulation is **activating** antigen presenting cell using an **RAR antagonist compound VIII**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XVII Claims 17, 19, 23-29 and 34, drawn to a **composition** for use in modulating the immune system of an animal wherein the modulation is **inhibiting** or preventing apoptosis of an antigen presenting cell using an RAR agonist wherein the **RAR agonist is an RARα agonist Compound I** or a pharmaceutical acceptable salts, esters or prodrugs thereof, a

specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XVIII. Claims 30-31 and 34, drawn to a **composition** for inducing apoptosis in a mammalian antigen-presenting cell comprising a pharmaceutical acceptable carrier and one synthetic retinoid wherein the retinoid is an **RARα agonist compound I**, or a pharmaceutically acceptable salt, ester or prodrug thereof, classified in Class 424, subclass 198.1, subclass 184.1.

XIX. Claims 30, 32 and 34, drawn to a **composition** for inducing apoptosis in a mammalian antigen-presenting cell comprising a pharmaceutical acceptable carrier and one synthetic retinoid wherein the retinoid is **RARβ agonist compound III**, or a pharmaceutically acceptable salt, ester or prodrug thereof, classified in Class 424, subclass 198.1, subclass 184.1.

XX. Claims 30, 32 and 34, drawn to a **composition** for inducing apoptosis in a mammalian antigen-presenting cell comprising a pharmaceutical acceptable carrier and one synthetic retinoid wherein the retinoid is **RARβ agonist compound VII**, or a pharmaceutically acceptable salt, ester or prodrug thereof, classified in classified in Class 424, subclass 198.1, subclass 184.1.

XXI. Claims 30, 33 and 34, drawn to a **composition** for inducing apoptosis in a mammalian antigen-presenting cell comprising a pharmaceutical acceptable carrier and one synthetic retinoid wherein the retinoid is **pan-RXR agonist SR11237**, and a pharmaceutically acceptable salt, ester or prodrug thereof, classified in classified in Class 424, subclass 198.1, subclass 184.1.

XXII. Claims 30, 33 and 34, drawn to a **composition** for inducing apoptosis in a mammalian antigen-presenting cell comprising a pharmaceutical acceptable carrier and one synthetic retinoid wherein the retinoid is **pan-RXR agonist compound V**, and a pharmaceutically acceptable salt ester or prodrug thereof, classified in classified in classified in Class 424, subclass 198.1, subclass 184.1.

XXIII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **infectious disease** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR SR11237**, a specific cytokine, one or more specific antigens and one or more

pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXIV. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **infectious disease** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR compound V** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXV. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **infectious disease** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound II** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXVI. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **infectious disease** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound V,** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXVII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **infectious disease** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound VIII**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXVIII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **infectious disease** comprising administering to an animal an effective amount of a specific composition comprising **RARα agonist Compound I** or a pharmaceutical acceptable salts, esters or prodrugs thereof, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXIX. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **parasitic disease** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR SR11237**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXX. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **parasitic disease** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR compound V** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXXI. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **parasitic disease** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound II** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXXII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **parasitic disease** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound V,** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXXIII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **parasitic disease** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound VIII**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1

XXXIV. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **parasitic disease** comprising administering to an animal an effective amount of a specific composition comprising **RARα agonist Compound I** or a pharmaceutical acceptable salts, esters or prodrugs thereof, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients classified in Class 424, subclass 198.1, subclass 184.1.

XXXV. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **immune system dysfunction** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR SR11237**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXXVI. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **immune system dysfunction** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR compound V** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXXVII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **immune system dysfunction** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound II** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XXXVIII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **immune system dysfunction** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound V**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424 subclass 198.1, subclass 184.1

IXL. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **immune system dysfunction** comprising administering to

an animal an effective amount of a specific composition comprising **RAR antagonist compound VIII**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XL. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **immune system dysfunction** comprising administering to an animal an effective amount of a specific composition comprising **RARα agonist Compound I** or a pharmaceutical acceptable salts, esters or prodrugs thereof, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XLI. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **Cancer** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR SR11237**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XLII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **Cancer** comprising administering to an animal an effective amount of a specific composition comprising retinoid **pan-RXR compound V** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XLIII. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **Cancer** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound II** a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XLIV. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **Cancer** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound V**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1

XLV. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **Cancer** comprising administering to an animal an effective amount of a specific composition comprising **RAR antagonist compound VIII**, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

XLVI. Claims 35-37, drawn to a method for treating or preventing a physical disorder wherein the physical disorder is a specific **Cancer** comprising administering to an animal an effective amount of a specific composition comprising **RARα agonist Compound I** or a pharmaceutical acceptable salts, esters or prodrugs thereof, a specific cytokine, one or more specific antigens and one or more pharmaceutically acceptable carriers or excipients, classified in Class 424, subclass 198.1, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups (XIII-XII) and Groups (I-XII, XXIII-XLVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in materially different process such as screening assays. Therefore, they are patentably distinct.

Inventions of Groups XIII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the various RAR specific receptor agonists and antagonists for different uses as claimed are unique products that differ with respect to their structures and physical properties. Therefore, they are patentably distinct.

Inventions of Groups I-XII and XXIII-XLVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of modulating immune system wherein the modulation is activating versus the method of inhibiting apoptosis, and the methods of treating specific disease using a

distinct RAR receptor agonist or antagonist differ with to the method steps and endpoints. Therefore, they are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

6. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121 to elect:
If Group I, II, III, IV, V or VI is elected, the Applicant is required to elect **a specific cytokine** such as the ones disclose on page 72 of the specification. These cytokines differ with respect to their structure and activity. Therefore, they are patentably distinct.

If Group XIII, XIV, XV, XVI or XVII is elected, the Applicant is required to elect **a specific cytokine** such as the ones disclose on page 72 of the specification and **a specific antigen** such as the ones disclose on page 74. These cytokines differ with respect to their structure and activity. Therefore, they are patentably distinct. These antigens are different with respect to their structures and physiochemical properties. Therefore, they are patentably distinct.

If Group XXIII, XXIV, XXV, XXVI, XXVII or XXVIII is elected, the Applicant is required to elect a **specific infectious disease** such as the ones disclose on page 75 of the specification, a specific cytokine such as the ones disclose on page 72 of the specification, and a specific antigen or antigens such as the ones disclose on page 74. These infectious diseases differ with respect to their etiology and treatment endpoints and therefore are patentably distinct. These cytokines differ with respect to their structure and activity and therefore are patentably distinct. These antigens are different with respect to their structures and physiochemical properties. Therefore, they are patentably distinct.

If Group XXIX, XXX, XXXI, XXXII, XXXIII or XXXIV is elected, the Applicant is required to elect a **specific parasitic disease** such as the ones disclose on page 75 of the specification, a specific cytokine such as the ones disclose on page 72 of the specification, and a specific antigen or antigens such as the ones disclose on page 74. These specific parasitic diseases differ with respect to their etiology and treatment endpoints. Therefore, they are patentably distinct. These

cytokines differ with respect to their structure and activity and therefore are patentably distinct. These antigens are different with respect to their structures and physiochemical properties. Therefore, they are patentably distinct.

If Group XXXV, XXXVI, XXXVII, XXXVIII, IXL or XL is elected, the Applicant is required to elect a **specific immune system dysfunction** such as the ones disclose on page 75 of the specification, a specific cytokine such as the ones disclose on page 72 of the specification, and a specific antigen or antigens such as the ones disclose on page 74. These specific immune system dysfunctions differ with respect to their etiology and treatment endpoints. Therefore, they are patentably distinct. These cytokines differ with respect to their structure and activity and therefore are patentably distinct. These antigens are different with respect to their structures and physiochemical properties. Therefore, they are patentably distinct.

If Group XLI, XLII, XLIII, XLIV, XLV or XLVI is elected, the Applicant is required to elect a **specific infectious disease** such as the ones disclose on page 75 of the specification, a specific cytokine such as the ones disclose on page 72 of the specification, and a specific antigen or antigens such as the ones disclose on page 74. These specific cancers differ with respect to their etiology and treatment endpoints and therefore are patentably distinct. These cytokines differ with respect to their structure and activity and therefore are patentably distinct. These antigens are different with respect to their structures and physiochemical properties. Therefore, they are patentably distinct.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1, 17 and 35 generic.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Due to the complexity of the claimed invention an oral restriction was not made.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
April 22, 2002

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600